Remarks

Entry of the foregoing and reconsideration of the application identified in caption as amended, pursuant to and consistent with the Rules of Practice in Patent Cases, and in light of the remarks which follow, is respectfully requested.

By the present amendment, claim 1 has been amended, claims 30-32 have been deleted, and new claims 33-43 have been added so that claims 1, 2, 4-15, 17-27, 29, and 33-43 will be pending. Presently, claims 1, 2, 4, 11, 12, 14, 15, 17-20, 27, 29, and 33-43 are under examination and claims 5-10, 13, and 21-26 have been withdrawn from consideration as being directed to non-elected invention(s). Support for the amendment to claim 1 can be found in the specification at least at page 21, lines 23 to 25. Accordingly, no new matter has been presented by the proposed amendments.

Claims 1, 2, 4, 11, 12, 14, 15, 17-20, and 27 stand rejected under 35 U.S.C. § 112, first paragraph for lack of written description. This rejection is respectfully traversed.

Claim 1 has been amended to recite a pH value in the range of from 1.5 to 3.5. This range is explicitly recited in the specification at page 21, lines 23 to 25. Accordingly, there is written description support for the present claims.

Withdrawal of the rejection under 35 U.S.C. § 112, first paragraph for lack of written description and allowance of the pending claims is respectfully requested.

Claims 1, 2, 4, 11, 12, 14, 15, 17-20, 27, 29, and 30 stand rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 6,004,538 to Hughes et al. ("Hughes") in view of U.S. Patent No. 4,568,540 to Asano et al. ("Asano"). This rejection is respectfully traversed.

The present invention pertains to liquid compositions for the desensitization of teeth including an acid, an organic polymer, a film-forming agent, and a solvent, having the recited properties and pH. It has been found by the present inventors that these compositions deeply penetrate into dentinal tubules. By reaction with dentinal fluid proteins they form massive plugs and thus reduce the sensitivity of the teeth (page 20, lines 1 to 8 and 17 to 23 of the present application). To achieve the desired formation of a plug, it is necessary to use acids having protein and calcium precipitating properties. The resulting formation of such plugs is surprising since acids usually have a sensitizing effect rather than a desensitizing effect (page 20, lines 7 to 8 of the present application).

The inventors have demonstrated that the compositions of the present invention result in the formation of massive plugs which deeply penetrate into dentinal

tubules (page 36, Example 8, in particular lines 31 to 35 in combination with Figures 3 and 5; page 36, line 38 to page 37, line 8; and Figure 6 of the present application) even if the natural pressure of dentinal fluid is simulated.

Present claim 1 is directed to a liquid composition comprising: a) a non-polymeric acid having protein and Ca precipitating properties; b) an organic polymer which has carboxyl groups and/or hydroxyl groups; c) a film forming component; and d) a solvent, e) and having a pH in the range of from 1.5 to 3.5.

The composition of Example 5 which is used in Example 8 comprises a first (acid) component: a) phosphonic acid (see specification, page 3, lines 8-12), second (polymer) component: b) polyacrylic acid + polyethylene glycol (page 19, lines 20-24), c) hydroxypropyl cellulose (page 21, lines 12-21) and d) ethanol/water (page 21, lines 33-37). It is explained at page 23 that the claimed compositions preferably comprise two components (acid component and polymer component). Further, Applicants submit the enclosed Declaration Under Rule 132 of Carlo Bolis, which shows that the composition of Example 8 as prepared in accordance with the procedure of Example 5 has a pH within the claimed range of from 1.5 to 3.5, i.e., namely a pH of 2.7.

Thus, the composition of Example 8 is within the scope of claim 1. The desensitization agents of the present invention result in a long-lasting desensitization effect. Formation of these plugs cannot be explained by the mere agglomeration of the polymers contained in the compositions. The experiments of the inventors clearly show that the simultaneous precipitation of polymer, dentinal fluid proteins and calcium is responsible for the formation of the plugs.

The claimed compositions include a combination of four components which are all needed to achieve the desired action:

1. The acid is responsible for conditioning the enamel and the dentine surface, respectively. The acid removes dentine debris and abrasives from dentifrices from the openings of the tubules so that the tubules are accessible for the protein and calcium precipitating components as well as for the co-precipitating polymers of the compositions of the present invention. The acid initiates the protein and calcium precipitation.
2. Precipitation is enhanced by the organic polymers having carboxyl and/or hydroxyl groups.

3. The precipitation reaction of the present invention usually requires 15 to 30 minutes. During this time period the tubules are protected by a film which is formed by the film forming agents.

This film protects the precipitation process and can easily be removed by toothbrushing or eating. This film is not needed to block the tubules, rather they are blocked by the plugs formed by the precipitation reaction of the acid and the organic polymers together with proteins and calcium from the dentinal liquor. These plugs are stable for 6 to 15 months.

Hughes discloses oral compositions which include a dimethicone copolyol anti-plaque agent and a dimethicone copolyol surfactant (column 3, lines 26-28). Depending on the intended use, the compositions may include further components. For instance, denture cleansing compositions can also incorporate an effervescence generator, i.e., a material which in the presence of water releases carbon dioxide or oxygen with effervescence (column 8, lines 4-8). However, these compositions are solid. Such effervescence generators typically contain at least one alkali metal carbonate or bicarbonate in admixture with an organic acid (column 8, lines 13-23). Hughes discloses the use of acids only in combination with effervescence generators, i.e., in compositions including an acid and also an alkali metal carbonate or bicarbonate, that is a component which reacts with the acid to form carbon dioxide and thus neutralizes the acid. Thus, the use of acids is disclosed only in combination with the solid compositions of Hughes. Moreover, compositions including acid and carbonate or bicarbonate are only stable in solid form because acid and carbonate or bicarbonate will immediately react in the presence of water (column 8, lines 35-37). Hughes does not disclose liquid compositions which include a free acid in combination with a solvent.

The Examiner indicated that the language of the claims of the present invention does not exclude effervescence generators. However, the compositions of Hughes that include effervescence generators must be solid because otherwise, the carbonate and the acid will immediately react in a liquid phase. Since present claim 1 is directed to liquid compositions, then the claimed composition can be distinguished from the effervescence generator-containing solid compositions of Hughes. Therefore, contrary to the Examiner's position, Hughes does not disclose (absent the pH) each element of the claimed composition of the present invention.

Asano relates to oral hygiene compositions which prevent and control mouth odor, calculus, plaque and caries and contain active zinc ions and fluoride ions (column 1, lines 5-12). These compositions contain a specific buffering system and have a pH of from about 3.5 to 6.0 (column 2, lines 28-29). A preferred buffering agent is sodium gluconate (column 3, lines 7-9). This buffering agent is used in all examples, i.e., in the examples no acid is used. Thus, the oral hygiene compositions of Asano are not desensitizing agents.

Asano does not disclose or suggest compositions including a non-polymeric acid and having a pH within the claimed range. In particular, claims drawn to a composition maintaining the pH range of 1.5 to 3.5 distinguish the compositions of Asano which have a pH between 3.5 and 6.0 (see also column 3, lines 17-19). Asano does not disclose a specific liquid composition having a pH of 3.5 or below. Moreover, Asano provides no reason to lower the pH to a value within the claimed pH range. Thus, the present claims which restrict the pH to a range of from 2 to 3 are further distinguished over Asano, for the same reason.

Furthermore, the Examiner's combination is based on hind sight. A skilled person not knowing the present invention would not have an incentive to combine the components as defined in present claim 1. Even if combined in the manner suggested, the proposed combination would not render obvious the presently claimed invention. The teachings of Hughes disclose either denture cleansing tablets, i.e. solid compositions including an effervescence generator, or toothpaste/denture cleansing pastes which have a gel structure and are not liquid. Furthermore, the toothpastes/denture cleansing pastes disclosed in Examples VI to VIII do not contain any fluoride and, therefore, a skilled person would not have adjusted the pH of these compositions to a range of 3.5 to 6 in order to stabilize the fluoride, as suggested by the Examiner.

The desensitizers of the present invention are not comparable with a dentifrice. Typically, a desensitization achieved by the use of a dentifrice only lasts for one day, i.e. a dentifrice has to be used daily.

It is the Examiner's position that Hughes discloses liquid dentifrices and mouthwash compositions including inter alia an effervescence agent, such as carbonate, in admixture with at least one organic acid, such as tartaric acid, fumaric acid, citric acid, malic acid, maleic acid, salicylic acid, succinic acid, gluconic acid, etc. In this regard the Examiner refers to column 8, lines 13 to 23 of Hughes.

Hughes discloses oral compositions such as toothpastes, toothpowders, liquid dentifrices, mouthwashes, denture cleansers, chewing gums, candies and the like (column 1,

lines 8 to 10). The inventors of the present application clearly differentiate between liquid compositions, such as mouthwashes which include a water/alcohol solution, flavor, humectant, sweetener, sudsing agent and colorant on the one hand, and solid compositions, such as denture cleanser compositions which can incorporate an effervescence generator on the other hand (column 7, lines 47 to 50 and column 8, lines 5 to 8 of Hughes). The denture cleansing compositions can be in paste, tablet, granular or powder form.

The effervescence generator is a material which in the presence of water releases carbon dioxide or oxygen (column 8, lines 5 to 8 of Hughes). For instance, the effervescence generator contains an acid and a carbonate and releases carbon dioxide upon reaction of the acid with the carbonate. It is evident that effervescence generators can only be used in solid compositions because the carbonate and the acid will immediately react in a liquid phase. Effervescence generators are commonly used as disintegration agents for tablets; they accelerate dissolution of the tablets when introduced into water. It is impossible and unnecessary to incorporate an effervescence generator into liquid compositions. According to Hughes, acids are only used as a component of the effervescence generator. It follows, that due to the presence of an effervescence generator Hughes do not disclose liquid compositions including an acid. Thus, the proposed combination of a solid composition containing an acid of Hughes with the pH range of Asano would not yield the present invention.

Furthermore, it should be noted that in all examples of Hughes an excess of alkaline reacting compound is used. In Examples I to V the ratio of base to acid is within a range of 1.3:1 (Example II) to 2.1:1 (Example I). This calculation takes into account that malic acid and citric acid are dibasic and tribasic acids, respectively, and that sodium carbonate is a dibasic base. Thus, upon dissolution of the solid compositions in water the base will completely neutralize the acid and an excess of base will remain rendering the solution alkaline. Moreover, Examples VI to VIII do not contain any acid at all. In contrast, the present claims are directed to acidic liquid compositions, for example, having a pH of 1.5-3.5. There is no reason to modify the Hughes solid compositions to a pH range of 1.5 to 3.5 simply because Asano teaches a variable pH range of from 3.5 to 6 for liquid compositions. The Examiner's basis for obviousness of the claimed pH range in view of the Asano pH range seems to be based upon both ranges being variable. However, a range is by definition variable and this is not a basis for obviousness of ranges.

Further, the liquid compositions of Hughes do not contain an acid. It is the Examiner's position that Asano specifically teaches that the pH of the compositions should be maintained at an acidic pH of 3.5 to 6 in order to permit the fluoride to remain in solution instead of precipitating and that the ordinary skilled artisan would have been motivated to maintain the pH of the compositions of Hughes at an acidic pH of from 3.5 to 6, with the expectation of maintaining the fluoride and zinc ions in solution.

Applicants rebut this assumption. In this regard, Asano tested different acids and came to the conclusion that:

> "not all organic acids are useful in the compositions of the present invention. Those acids that result in the formation of a precipitate or haze (start of precipitate) would not be useful since they would result in a reduction in the available fluoride ions and zinc ions." (column 8, lines 21 to 26)

Thus, while claim 1 of the present invention requires the use of an acid having protein and calcium-precipitating properties, Asano suggests the use of acids which do not form a precipitate or haze. Asano directly teaches away from using an acid having protein and calcium-precipitating properties. Thus, it follows that even if a skilled person had combined the teachings of Hughes and Asano in the manner presently proposed, he would not have arrived at the claimed invention. If a skilled person had used an acid to adjust the pH of the liquid composition of Hughes, according to Asano, he would have used a non-precipitating acid.

In this regard it is noted that according to Table II in column 8 of Asano the addition of maleic acid results in the formation of a clear solution having a pH of 4.6. Thus, when using this acid, a skilled person would have adjusted the pH to 4.6, not from 1.5 to 3.5, or 2 to 3 as suggested by the present invention (maleic acid is mentioned at page 18, lines 21 to 22 of the present application). For at least the reasons noted above, the proposed combination of Hughes and Asano clearly teaches away from the present invention.

The present inventors found that liquid compositions including acids having protein and calcium-precipitating properties in combination with an organic polymer which has carboxyl and/or hydroxyl groups, a film forming component and a solvent, and having the claimed pH are useful in the treatment of sensitive teeth. The activity of these compositions is based on a precipitation reaction (page 20, lines 16-23 of the application) which occurs in the dentinal tubules. In this regard the precipitation of fluoride ions is said to

be advantageous (see page 21, lines 4-7). In contrast to this Asano teaches the use of non-precipitating acids and the use of a pH range which avoids the precipitation of Zn and F ions.

Accordingly, for at least the reasons noted above, the proposed combination of Hughes and Asano would not render obvious the presently claimed invention. Withdrawal of the record rejection and allowance of all claims is respectfully requested.

From the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order, and such action is hereby earnestly solicited.

Respectfully submitted,

Date: July 21, 2009

/Joseph M. Noto/
Joseph M. Noto
Registration No. 32,163

NIXON PEABODY LLP
1100 Clinton Square
Rochester, New York 14604-1792
Telephone: (585) 263-1601
Facsimile: (585) 263-1600